

REMARKS

Claims 16-19, 21-38, 49-74 and 76-91 are pending in the present application. Applicants have canceled claims 17-19, 21-24 and 66-74 without prejudice and amended claims 16, 25, 26, 34 and 87. Claims 25, 26, 34 and 87 are amended to change their dependency. Support for the amendments to claim 16 can be found, *inter alia*, in the original claims 19 and 24 and on page 19, lines 30-33 of the original specification. Therefore, these amendments are fully supported by the original specification and do not raise any issue of new matter. Accordingly, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 16, 25-38, 49-65 and 76-91 will be under examination.

PRIORITY

Applicants intend to rely on the filing date of the prior Application No. 60/527,084, filed on December 4, 2003. Applicants note that M.P.E.P. 201.11 requires that "a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet" and that "the specific reference to any prior nonprovisional application must include the relationship between the applications."

In this case, Applicants have included a specific reference, including the relationship between the two applications, to the prior Application No. 60/527,084, filed on December 4, 2003 in the Application Data Sheet, a copy of which is hereby enclosed. Applicants believe that such a specific reference to the prior Application No. 60/527,084 satisfies the requirement of M.P.E.P. 201.11. However, for the convenience of the Patent Office, Applicants have amended the specification to incorporate such specific reference to the prior Application No. 60/527,084 into the first sentence of the specification. Therefore, this ground of objection is moot.

OBJECTION TO THE SPECIFICATION

Applicants have amended the abstract to delete the objected terms. Applicants have also amended the specification to insert the missing U.S. Patent Application Serial Numbers. Therefore, this ground of objection is moot.

CLAIM OBJECTION

Claims 33 and 87 stand objected as being in improper form. Applicants note, however, that the objected claims should be claims 34 and 87. Applicants have amended claims 34 and 87 to be dependent upon claims 31 and 76, respectively. Therefore, this ground of objection is moot.

REJECTION OF CLAIMS UNDER 35 U.S.C. 102(b)

Claims 16-18, 21-23, 36, 49-55, 60, 61-68, 70-73, 76-82, 87, 90 and 91 stand rejected under 35 U.S.C. 102(b) as being anticipated by Curatolo et al., U.S. Patent No. 6,068,859 ("Curatolo").

In order to expedite the prosecution of the present application, without conceding to the correctness of the Office Action rejection, Applicants have canceled claims 17-18, 21-23, 66-68 and 70-73 without prejudice and amended claim 16 to incorporate the elements of claims 19 and 24 which are not deemed not being anticipated by Curatolo. Therefore, the rejection of claim 16, as amended, is moot.

In addition, Curatolo does not anticipate claims 36, 49-55, 60, 61-65, 76-82, 87, 90 and 91 because they are dependent upon claim 16, either directly or indirectly, and incorporate all the elements of claim 16. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

REJECTION OF CLAIMS UNDER 35 U.S.C. 102(a)

Claims 16-19, 21-38, 49-74, and 76-91 stand rejected under 35 U.S.C. 102(a) as being obvious over Curatolo in view of WO 03/032922 and further in view of Constantinides et al., U.S. Patent No. 6,479,540 B1 ("Constantinides"). The Office Action admitted that "Curatolo does not teach all the glycerides listed by applicants. Specifically, the reference does not disclose the use of glyceryl behenate." *Office Action at page 8*. The Office Action also admitted that "Curatolo does not disclose the use of poloxamer 407 as a dissolution enhancer" and "Curatolo also does not disclose the use of magnesium hydroxide

and tribasic sodium phosphate as the alkalizing agents.” *Id at 8.*

Applicants respectfully point out that the Office Action fails to establish a *prime facie* case of obviousness under the standard of M.P.E.P. § 2142 which states that:

to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

The Office Action does not meet at least the first and third requirements. Specifically, Curatolo, WO 03/032922 and Constantinides does not specifically teach or suggest the use of glyceryl monobehenate, glyceryl dibehenate, glyceryl tribehenate or a mixture thereof to prepare azithromycin-containing multiparticulates. Applicants note that the Office Action pointed to WO 03/032922 as teaching the specific glyceride, glyceryl behenate on page 8. However, WO 03/032922 suggested that glyceryl behenate, together with long list of other chemicals, can be used as a lubricant in forming tablets and “lubricants generally comprise 0.5 to 7.0% of the total tablet weight.” WO 03/032922 does not teach or suggest the use of about 25% to about 80% of a glyceride which comprises glyceryl monobehenate, glyceryl dibehenate, glyceryl tribehenate or a mixture thereof to form azithromycin-containing multiparticulates.

Moreover, without looking at the disclosure of the present application, one of ordinary skill in the art would not know from the combination of Curatolo, WO 03/032922 and Constantinides how to select the an effective amount of an alkalizing agent, a poloxamer and multiparticulates which comprise about 20% to about 75% azithromycin, and about 25% to about 80% of a glyceride which comprises glyceryl monobehenate, glyceryl dibehenate, glyceryl tribehenate or a mixture thereof having the advantages described in the specification, e.g. reducing the diarrhea, nausea and vomiting. In fact, page 62 of the original specification shows, in table 6, that one of the claimed oral dosage form, SR15,

provided a relative degree of improvement, as compared to the control, of 1.6 for diarrhea (from 27.8% to 17.9%), 3.2 for nausea (from 54.6% to 17.0%) and 9.3 for vomiting (from 25.9% to 2.8%). Therefore, the Office Action does not satisfy the first criteria for establishing a *prime facie* case of obviousness under M.P.E.P. § 2143.01 because the "suggestion or motivation" criteria must be satisfied from the disclosure of the prior art reference or from the knowledge of persons skilled in the art, not by the use of hindsight in view of the present application (emphasis added).

In this case, even assuming that Curatolo, WO 03/032922 and Constantinides can be combined, the combination does not disclose "all the claim limitations." In particular, Curatolo does not specifically teach the use of glyceryl behenate in making multiparticulates and neither WO 03/032922 nor Constantinides teaches the incorporation of about 25% to about 80% of glyceryl monobehenate, glyceryl dibehenate, glyceryl tribehenate or a mixture thereof into azithromycin-containing multiparticulates. Therefore, the Office Action fails to satisfy the third criteria for establishing a *prime facie* case of obviousness under the M.P.E.P. § 2143.01.

In addition, Applicants have achieved superior results by selecting an effective amount of an alkalizing agent, a poloxamer and multiparticulates which comprise about 20% to about 75% azithromycin, and about 25% to about 80% of a glyceride which comprises glyceryl monobehenate, glyceryl dibehenate, glyceryl tribehenate or a mixture thereof to substantially reduce the occurrence of diarrhea, nausea and vomiting. In one example, SR15, Applicants achieved a relative degree of improvement, as compared to the control, of 1.6 folds for diarrhea (from 27.8% to 17.9%), 3.2 folds for nausea (from 54.6% to 17.0%) and 9.3 folds for vomiting (from 25.9% to 2.8%). Therefore, the claims are nonobvious over the disclosure of Curatolo, WO 03/032922 and Constantinides as "superiority of a property shared with the prior art is evidence of nonobviousness," M.P.E.P. § 716.02 (a). Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CONCLUSION

In view of the claim amendments and the remarks, further and favorable consideration of all pending claims are respectfully requested.

It is believed that no fee is deemed necessary in connection with the filing of the present Amendment. However, if any fees are required, the Commissioner is hereby authorized to charge any such fees to our Deposit Account No. 16-1445.

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Respectfully submitted,

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